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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/597,980 | 08/15/2006 | Jorn Borgert | DE040046 | 8813 |
| 24737 | 7590 | 08/18/2009 | EXAMINER | |
| PHILIPS INTELLECTUAL PROPERTY & STANDARDS | | | GUPTA, VANI | |
| P.O. BOX 3001 | | | | |
| BRIARCLIFF MANOR, NY 10510 | | | ART UNIT | PAPER NUMBER |
| | | | 3768 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 08/18/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/597,980 | BORGERT ET AL. | |
| | Examiner | Art Unit | |
| | VANI GUPTA | 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 and 11 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-9 and 11 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. ***Claims 1 – 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Twiss et al. (US 5,375,596).***

Regarding claims 1 and 2, Twiss *et al.* (hereinafter *Twiss*) a first catheter element – a catheter assembly (30), and a second catheter element – a guidewire assembly (22), wherein the first and the second catheter element are coupled in such a manner that a sliding movement relative to each other is possible. That is, the guidewire assembly is fitted so that it can be inserted and removed from the catheter (*col. 4, lines 1 – 8 and lines 32 – 47*), thereby inherently creating a sliding action between the two assemblies.

Regarding claims 1 and 4, Twiss also discloses first and second active localizers, such that the first localizer is placed on the catheter assembly, so that the catheter's spatial position can be determined with at least a second active localizer placed on it, whose spatial position can be determined. A *transmitter/detector unit* (2), which is common to both the catheter and guidewire, comprises a housing unit with an antenna (14) that transmits a RF alternating current (AC) signal to the each the antenna(s) that is/are attached to each the catheter and guidewire (*col. 4, lines 16 – 23*). The RF AC signal transmits a magnetic field that is detected by either of the guidewire antennna(s) and/or catheter antenna(s) (*col. 6, lines 50 – 65*).

Furthermore, the first (28) and the second (32) active localizers are capable of being used simultaneously to determine the spatial positions of the first and second active localizers with respect to each other, since both localizers (antennas) are used to transmit and receive positional information (col. 4, line 66 – col. 5, line 26) to position the catheter (34) relative to the guidewire (23 or 24). Therefore, the localizers are being used to determine each other's positions relative to each other (col. 7, lines 51 – 58).

Regarding Claim 3, Twiss explains that his catheter is designed so that it is capable of being fixed in a surrounding vessel, such that the guidewire may be removed from the vessel while the catheter stays in place (*col. 9, lines 26 – 41*).

Regarding Claim 5, Twiss explains that his guidewire comprises antenna(s) that is/are capable of “radiat[ing]” an RF AC magnetic field (*col. 13, lines 5 – 8*).

Regarding claims 7 and 8, Twiss also discusses method(s) for performing catheter navigation, using the aforementioned components (*please refer to the same passages mentioned above; and col. 7, lines 51 – 58; col. 9, lines 6 – 61*). With respect to determining the a spatial position of the first active localizer and determining a spatial position of the second active localizer, wherein the determination is performed substantially simultaneously, Twiss discusses the positioning of the guidewire can be performed as a “real-time path and tip location” process (*col. 8, line 37*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. *Claims 6 and 11 are rejected under 35 USC 103(a) as being obvious over Twiss et al.*

(US 5,375,596) as applied to Claim 1 above.

Regarding claims 6 and 11, Twiss discloses the catheter system as claimed in Claim 1.

Twiss also explains that a fine wire antenna, for tracking purposes, may run along the entire length of both the catheter elements. Therefore, the localizers are close enough to each other so that Twiss's system is capable of performing within the limitations of Claim 1.

However, Twiss differs from claims 6 and 11 in that Twiss does not specifically suggest the localizers are arranged at a distance of less than 10 cm, as claimed in Claim 6, or less than 5 cm from each other, as claimed in Claim 11, during use of the catheter system.

Nonetheless, it would be obvious to one of ordinary skill in the art at the time of the invention was made to arrange the localizers as claimed above, since it has been held that rearranging parts of an invention involves only routine skill in the art. See *In re Japikse*, 86 USPQ 70.

Furthermore, Applicant has not disclosed that such a specific arrangement between the active localizers solves any stated problem or is for any particular purpose, except for the fact "the distance between the localizers does not exceed [a] top limit, so that they are exposed to external influences to an almost equal extent" (Specification, p. 4, lines 1 – 6), and therefore it appears that the present invention would perform equally well with the arrangement of Twiss.

2. *Claim 9 is rejected under 35 USC 103(a) as being obvious over Twiss et al. (US 5,375,596), as applied to Claim 7 above, in further view of Kucharczyk et al. (US 2006/0074295 A1).*

Regarding Claim 9, Twiss discloses a method for navigating a catheter system in a vascular system, as explained above.

However, Twiss differs from Claim 9 in that he does not appear to specifically disclose generating an image of the vascular system with the catheter system contained in it, and in that the spatial position of the first localizer relative to the vascular system is determined on this image.

Nonetheless, *Kucharczyk et al. (hereinafter Kucharczyk)* teaches iamging methods that can be used to assist in the determination of devices located in within a patient (paragraph [0016]).

It would have been prima facie obvious to modify Twiss with the teachings of Kucharczyk to include an imaging method for the fact that *Kucharczyk* actually incorporates Twiss in his teachings of his invention (*paragraph [0006]*) for the purposes of including Twiss' method and apparatus for determining the position of devices such as the aforementioned catheter system

Response to Arguments

1. Applicant's arguments, see paragraph 2 p. 4 of Remarks, filed May 7, 2009, with respect to 35 USC 112 rejection second paragraph rejection have been fully considered and are persuasive. The rejections of claims 3 and 6 have been withdrawn.

2. Applicant's arguments filed May 7, 2009 with respect to 35 USC 102(b) rejection of claims 1 – 8 and 10 have been fully considered but they are not persuasive.

In response to Applicant's arguments that Twiss does not determine spatial positions of the two antennas/localizers with respect to each other, Examiner points out that this refers to intended use or functional limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, it then meets the claim.

However, Examiner points that Twiss indeed does teach using simultaneously the first (28) and the second (32) active localizers to determine the spatial positions of the first and second active localizers with respect to each other, since both localizers (antennas) are used to transmit and receive positional information (col. 4, line 66 – col. 5, line 26) to position the catheter (34) relative to the guidewire (23 or 24). Therefore, the localizers are being used to determine each other's positions relative to each other (col. 7, lines 51 – 58) as the catheter and guidewire are being positioned relative to each other based on this localizer-information. Additionally, Twiss discusses the positioning of the guidewire can be performed as a “real-time path and tip location” process; i.e., Twiss substantially simultaneously determines the spatial position of the first active localizer and the spatial position of the second active localizer (col. 8, line 37).

3. Applicant's arguments with respect to claim 9 have been considered but are moot in view of the aforementioned explanations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768